



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Boyce, Todd M. et al. **EXAMINER:** Koh, C.
SERIAL NO.: 09/610,026 **GROUP ART UNIT:** 3738
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FOR: OSTEOGENIC IMPLANTS **DATED:** October 9, 2001
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Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to the examination of the above-identified application on the merits, please amend the subject patent application as follows:

IN THE SPECIFICATION:

On page 1, please insert the following paragraph after the title:

--CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of co-pending U.S. Application Serial No. 09/610,026, filed on July 3, 2000.--

CERTIFICATION UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence and the documents referred to as enclosed are being deposited with the United States Postal Service on date below in an envelope as "Express Mail Post Office to Addressee" Mail Label Number **EL913582794US** addressed to: Assistant Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

Dated: October 9, 2001



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IN THE CLAIMS:

Please cancel Claims 1-13 and 33-35 without prejudice.

Please examine Claims 14-32 and 36-40 as follows:

14. A method of forming an osteogenic osteoimplant having not greater than about 32% void volume, the method comprising:

providing a coherent mass of bone particles optionally in combination with one or more biocompatible components, the coherent mass formed at least in part from elongate bone-derived elements optionally in combination with bone powder; and,

mechanically shaping the coherent mass of bone particles to form the osteogenic osteoimplant.

15. The method of Claim 14 wherein the bone particles are obtained from cortical, cancellous and corticocancellous bone of autogenous, allogenic, xenogenic and transgenic origin.

16. The method of Claim 14 wherein the biocompatible component is selected from the group consisting of biocompatible fluid carrier, biocompatible binder, filler, fiber, mesh, substance providing radiopacity, plasticizer, biostatic/biocidal agent, surface active agent, and bioactive substance.

17. The method of Claim 14 which further comprises applying heat to the composition before, during or after mechanically shaping the coherent mass.

18. The method of Claim 14 which further comprises cross-linking bone particles within the composition before, during or after mechanically shaping the coherent mass.

19. The method of Claim 14 which further comprises dehydrating the composition before, during or after mechanically shaping the coherent mass.
20. The method of Claim 17 which further comprises dehydrating the heated, mechanically shaped coherent mass after applying the heat.
21. The method of Claim 14 wherein the step of mechanically shaping comprises pressing, extruding and/or rolling.
22. The method of Claim 21 further comprising means for the application of lateral force.
23. The method of Claim 22 wherein a compressive and lateral force is applied simultaneously.
24. The method of Claim 14 further comprising the step of placing the coherent mass between two flexible stick-resistant surfaces prior to the step of mechanically shaping.
25. The method of Claim 14 further comprising the step of placing the coherent mass of bone-derived particles on an inflexible, impermeable, horizontally planar work surface prior to the step of mechanically shaping.

26. The method of Claim 25 wherein the step of mechanically shaping further comprises contacting the coherent mass with at least one revolving cylindrical roller.
27. The method of Claim 26 wherein at least one of the revolving cylindrical roller is modified to provide for the surface treatment of one or both surfaces of the osteoimplant.
28. The method of Claim 14 further comprising the step of:
occluding a portion of the surface area of the osteoimplant to provide at least one zone of impermeability to soft tissue ingrowth wherein said zone is integral with the osteoimplant.
29. The method of Claim 28 wherein the occluding step comprises heating a portion of the surface area at elevated temperature.
30. The method of Claim 28 wherein the occluding step comprises crosslinking bone particles at a portion of the surface area of the mechanically shaped mass.
31. The method of Claim 14 further comprising the step of shaping the osteoimplant to a determined form, configuration and/or three-dimensional architecture.
32. The method of Claim 14 further comprising the step of layering and fastening the osteoimplant to form a laminate material.
36. An osteoimplant prepared by the method of claim 14.
37. An osteoimplant prepared by the method of claim 17.

38. An osteoimplant prepared by the method of claim 26.
39. An osteoimplant prepared by the method of claim 28.
40. An osteoimplant prepared by the method of claim 31.

REMARKS

Claims 14-32 and 36-40 are now under examination.

Claims 1-13 and 33-35 have been canceled without prejudice.

An early and favorable action on the merits of Claims 14-32 and 36-40 presented herein are respectfully requested.

Respectfully submitted,



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